IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: All Cases	

PLAINTIFFS' STEERING COMMITTEE'S RESPONSE IN OPPOSITION TO BESINS HEALTHCARE INC.'S AND BESINS HEALTHCARE, S.A.'S MOTION FOR SUMMARY JUDGMENT

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April 20, 18

INTRODUCTION

Besins Healthcare, S.A. ("Besins S.A.") and Besins Healthcare Inc. ("Besins Inc.") (collectively referred to herein as "Besins" or "the Besins defendants"), argue that Plaintiffs only remaining claims against them are strict liability design defect and negligent manufacturing and design. Defendants are wrong.

Plaintiffs continue to bring four causes of action against the Besins defendants: (1) strict liability (design defect); (2) negligence; (3) redhibition; and (4) unjust enrichment.[1] Disputed issues of material fact preclude summary judgment as to these remaining claims.[2]

As the Court has summarized Plaintiffs' allegations against the Besins defendants before:

> (1) the Besins defendants were involved in the design or manufacture of AndroGel; (2) AndroGel's unreasonably dangerous side effects rendered it defective; (3) AndroGel's defective design injured plaintiffs; and (4) the Besins defendants acted negligently in designing the drug, should be held strictly liable for the drug's defective design, and should be held liable for the price of the drugs to buyers who would not have purchased them had they known of the defects.

Mem. Op. and Order, September 3, 2015 at 14.

Besins Inc. co-owns the AndroGel patent with AbbVie Inc. ("AbbVie"). *See* Ex. 2, MacAllister Tr. 25:20-21; 26:4-11; 56:2-7. Besins Inc. was primarily "responsible for the relationship with AbbVie in the United States," which included joint AndroGel steering

[1] As well as derivative claims for wrongful death, survival action, loss of consortium, and punitive damages.

[2] Although summary judgment was entered against Plaintiff Robert Rowley on his claims against Besins, that was due in part to an incomplete factual record at the time, but also due to the specific causes of action he brought under Utah law, and because he did not bring an unjust enrichment claim. *See* CMO 50 (Master Dkt. No. 1899); *see also Rowley* Compl. (15-cv-2760 Dkt. No. 1).

committees and boards. *Id.* at 28:1-31:1; 56:8-16. "All aspects of the product," such as patent, supply, sales, and marketing issues, were presented and discussed. *Id.* at 29:12-24.

Besins S.A. and AbbVie have a Safety Data Exchange Agreement pursuant to which Besins S.A. collects reports of AndroGel adverse events and maintains the worldwide pharmacovigilance database of adverse events reported from any country in the world where AndroGel is used, including the United States. Besins S.A. is responsible for evaluating reports of adverse events and providing AndroGel risk information to AbbVie. Besins S.A. also receives reports of adverse events and safety information for AndroGel from AbbVie. Despite its role in maintaining the worldwide pharmacovigilance database for AndroGel, and despite its responsibility to evaluate adverse event information and to conduct safety surveillance for AndroGel, Besins S.A. failed to exercise due care by failing to take adequate steps to evaluate the evidence of a causal association between the use of AndroGel and cardiovascular events and venous thromboembolism ("VTE"). Besins S.A. was negligent in failing to notify AbbVie of this evidence of a causal association between the use of AndroGel and both cardiovascular and VTE injuries, which in turn resulted in AbbVie's failure to provide an adequate warning of this risk to prescribing healthcare providers in the United States, including those who prescribed AndroGel to Plaintiff. Besins Inc., as the primary contact with AbbVie, similarly failed. This negligence was the proximate cause of Plaintiffs' injuries. As Plaintiffs have alleged *ad nauseum*, AndroGel is defective: it is a dangerous product that has not been adequately tested before Besins and AbbVie introduced it to the U.S.

market. Lastly, the Besins defendants have known of these dangers and have unjustly benefited from the lucrative sales of the product in the United States.

Besins' motion for summary judgment should be denied because there are genuine disputes of material fact that must be resolved by the jury.

LEGAL STANDARD

This Court has set forth the legal standard to be applied on a motion for summary judgment in several of its rulings. *See, e.g.,* CMO 76, Master Dkt. No. 2210 (October 23, 2017) at 12.

ARGUMENT

I. DISPUTED ISSUES OF FACT PRECLUDE SUMMARY JUDGMENT FOR BESINS S.A. AND BESINS INC. ON PLAINTIFFS' REMAINING CLAIMS

A. Strict Liability – Design Defect

The Besins defendants argue that Plaintiffs' strict liability design defect claim fails because Plaintiffs do not have evidence that AndroGel's design was inadequate or that there was a defect in its physical design. Defs.' Mot. at 7. The Court rejected this argument before.

> Defendants' additional argument that the complaint "lacks even the most basic information regarding what, if any, supposed defect . . . exists," Defs.' Reply Br. at 9, is simply untrue. **The master complaint contains detailed allegations about the health hazards and risks of TRT drugs (including the formation of blood clots and other cardiovascular injuries), as well as the mechanism by which TRT drugs create those risks.** Plaintiffs' complaint thus provides much more than "bare allegation[s] that the [product] suffered from a 'design defect'," *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010), or allegations that "never even identif[y] what the supposed defect" is, *Ball v. Takeda Pharm. Am., Inc.*, 963 F. Supp. 2d 497, 505 (E.D. Va. 2013).

Mem. Op. and Order, September 30, 2015 at 15 (emphasis added). As this Court correctly pointed out at the time, "plaintiffs allege that the TRT drugs' defective design made them unreasonably dangerous but that 'Defendants' knowingly introduced the drugs into the

market and plaintiffs sustained their injury as a direct and proximate cause of 'Defendants' manufacture … of the defectively designed drugs." *Id.*, *citing* Master Compl. at ¶ 477. The Besins defendants offer no new arguments and, accordingly, their motion should be denied.[3]

B. Redhibition

Defendants also argue that Plaintiffs' redhibition claim fails because the claim is similar to one for a breach of an implied warranty and Plaintiffs conceded to the dismissal of that claim. While it is true that Plaintiffs' conceded to the dismissal of their implied warranty claims against the Besins defendants, at the same time that they did so, Plaintiffs objected to the dismissal of their redhibition claim and the Court agreed:

> In support of Claim Eight, plaintiffs allege that the TRT drugs' defect rendered them useless or their use so inconvenient that buyers would not have used them had they known of the defect. In the alternative, plaintiffs allege that the TRT drugs' defect so diminished their value that buyer would have purchased them for a lesser price had they known of the defect.

Mem. Op. and Order, September 30, 2015, at 4; 18-20 (denying dismissal of Plaintiffs' redhibition claim as to the Besins defendants). Moreover, Plaintiffs' redhibition claim is more akin to its design defect claim. *See* La. Civ. Code Ann. T. 2520 (A plaintiff bringing a redhibition claim must prove that the product's defect "renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect."). For the same reasons that Plaintiffs' strict liability design defect claim should survive, and because the Besins defendants fail to offer any

[3] The Besins defendants also assert that, as "a matter of policy," design defect claims are generally preempted in pharmaceutical cases under *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013). That argument has been rejected by this Court. *See, e.g.*, CMO 76, Dkt. No. 2210 at 26. Plaintiffs respectfully submit that the Court should continue to do so.

additional arguments as to why the Court should now enter judgment against Plaintiffs' redhibition claim, Defendants' motion should be denied.

C. Negligence

The Besins defendants argue that the "only possible avenue for them to remain in this case is if Plaintiffs have articulated a specific design or manufacturing defect that is actionable under a particular state's law." Defs.' Br. at 5. But Plaintiffs' negligence claim is not limited to design and manufacturing defect allegations. The Besins defendants have failed to provide any support, factual or legal, for summary judgment on Plaintiffs' negligence claims that relate to their role with respect to pharmacovigilance and their failure to conduct sufficient testing of AndroGel. The Besins defendants' motion should therefore be denied as to the negligence claim on that basis alone. Moreover, the Besins defendants' motion should be denied because issues of disputed fact preclude summary judgment.

1. Besins S.A. and Besins Inc. Had A Duty to Exercise Due Care when They Created AndroGel and Undertook Pharmacovigilance and Reporting Obligations with Respect to AndroGel

Besins S.A. designed and developed the AndroGel product. Master Answer of Defendant Besins Healthcare, S.A. ¶ 55-56, Dkt. No. 1589. Besins S.A. has a Licensing Agreement and Supply Agreement with AbbVie regarding the manufacture and distribution of AndroGel in the United States. *See* Defs.' Br. at ¶ 9. Additionally, Besins S.A. collects reports of AndroGel adverse events and maintains the worldwide pharmacovigilance database of adverse events reported from any country in the world where AndroGel is used, including the United States. Pltf. Statement of Facts, ¶ 12-21. Besins S.A. is responsible for evaluating reports of adverse events for AndroGel from all

over the world and providing AndroGel risk information to AbbVie. *Id*. Besins S.A. also receives reports of adverse events and safety information for AndroGel from AbbVie. *Id.*

Besins Inc. co-owns the AndroGel patent with AbbVie. *See* Ex. 2, MacAllister Tr. 25:20-21; 26:4-11; 56:2-7. Besins Inc. was primarily "responsible for the relationship with AbbVie in the United States," which included joint AndroGel steering committees and boards. *Id*. at 28:1-31:1; 56:8-16. "All aspects of the product," such as patent, supply, sales, and marketing issues, were presented and discussed. *Id.* at 29:12-24.

Besins created AndroGel and has received substantial revenue, millions of dollars annually, as a result of the sale of AndroGel in the United States. Ex. 13; Ex. 1 at 18:14-21:11; and Ex. 2 at 183:8-188:8. Further, both Besins S.A. and Besins Inc. had regular meetings with AbbVie during which it received reports of AndroGel sales to patients in the United States. Ex. 1, Besins 30(b)(6) Tr. at 28:1-29:24; 34:10-54:13; 59:17-64:4; 83:3-10. As a result, the Besins defendants knew that hundreds of thousands of patients in the United States use AndroGel each year. The Besins defendants knew that inadequate testing has been done regarding cardiovascular and VTE risks associated with AndroGel:

> Objectively speaking there is not sufficient evidence on either side to draw a conclusion and the community should be calling for further study. Of course, that begs the question of who has the responsibility for that. The most obvious choice would be AbbVie and I suspect they are very well keeping their heads down to avoid this discussion. Derivatively, we are the second best candidate and we should be very careful too about getting into this discussion. Our company has also benefited financially along with AbbVie and I can easily see the discussion turning towards some kind of ethical obligation to society on the parts of those who have benefited to support addressing an important (and expensive) safety concern.

Ex. 14. The Besins defendants also knew or should have known that patients would foreseeably suffer injuries as a result of their failure to exercise ordinary care in testing

the product and carrying out its pharmacovigilance, signal detection, and adverse event assessment responsibilities. *Id.*

2. The Besins Defendants Breached their Duty by Failing to Test AndroGel and Adequately Communicate AndroGel's Risks to AbbVie and Regulators

Despite its role in creating the product and maintaining the worldwide pharmacovigilance database for AndroGel, and despite its responsibility to evaluate adverse event information and to conduct safety surveillance for AndroGel, Besins failed to exercise due care by failing to take adequate steps to evaluate the evidence of a causal association between the use of AndroGel and cardiovascular and VTE injuries. Besins failed to adequately test AndroGel and failed to notify AbbVie or the FDA of the evidence of a causal association between the use of AndroGel and cardiovascular and VTE injuries, which also in turn directly contributed to AbbVie's failure to provide an adequate warning of these risks to prescribing healthcare providers in the United States.

Besins further breached its duty by failing to communicate the risk of cardiovascular and VTE injuries with AndroGel to other TRT manufacturers, to testosterone experts in the United States, and to U.S. regulators at the FDA. Besins contributed to the Advisory Committee Industry Briefing Document submitted to the U.S. Food and Drug Administration. Ex. 11-12. The Briefing Document was submitted in advance of the Advisory Committee Meeting held by the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA, which held its Advisory Committee Meeting on September 17, 2014. Ex. 12. The Briefing Document is described as a "consensus document reflecting the views of the 12 collaborating TRT Sponsors on the above topics."

Id. Besins Healthcare is identified as one of the TRT Sponsors that contributed to the briefing book. *Id.* The FDA held the Advisory Committee meeting "to discuss the appropriate indicated population for testosterone therapies and the potential for cardiovascular risk associated with this use." *Id.*

Additionally, Besins sponsored a "KOL[4] meeting" of testosterone experts in connection with the FDA Advisory Committee Meeting in September 2014. Ex. 12; Ex. 1 at 28:1-14. The meeting was held in Herndon, Virginia and was attended by "subject matter experts" in the field of testosterone, by representatives of AbbVie, and by representatives of Besins. *Id.* Besins employees Paul Piette and Jean-Paul Dutret, "medical liaisons" employed by Besins, were in attendance at the meeting. Ex. 1, Bua Tr. 67:21-69:15. Mr. Piette was "responsible for medical affairs worldwide ex-U.S." and Mr. Dutret was responsible for "worldwide global ex-U.S. pharmacovigilance." Ex. 1 at 69: 6-15. Jay Bua, President of Besins Inc., who also sits on the Board of Directors for Besins S.A. attended the KOL meeting. *Id.* at 68:21-69:5.

Despite having participated in discussions that are at the heart of Plaintiffs' case, and despite its role in maintaining and monitoring worldwide AndroGel pharmacovigilance, Besins failed to communicate the information available to it regarding cardiovascular and VTE risk; failed to alert AbbVie and other sellers and manufacturers to this risk, and ultimately this failure resulted in inadequate warnings of this risk to healthcare providers in the United States.

[4] KOL is an industry abbreviation for "Key Opinion Leader" and is a reference to "testosterone experts" in attendance at the meeting. *See* Ex. 1 at 68: 5-9.

3. Besins' Negligence Proximately Caused Plaintiffs' Injuries

Besins' failure to take adequate steps to test AndroGel's risks and monitor the available safety data and to notify AbbVie and the FDA regarding the evidence of a causal association between AndroGel and cardiovascular and VTE injuries directly resulted in an inadequate warning of these risks to Plaintiffs' and their prescribing physicians. Plaintiffs respectfully submit that disputed issues of fact preclude summary judgment with respect to proximate causation.

D. Unjust Enrichment

The Besins defendants do not make a particular argument for summary judgment regarding Plaintiffs' unjust enrichment claim and, instead, mistake the claim as one that is merely "seeking damages pursuant to the three remaining causes of action." *See* Defs.' Br. at 1. Defendants have failed to appreciate that, under the laws of several states, unjust enrichment is a separate cause of action rather than a derivative claim like loss of consortium. *See, e.g., In re Processed Egg Prods. Antitrust Litig.*, 851 F.Supp.2d 867, 913-914 (E.D. Pa. 2012) (California and Mississippi treating unjust enrichment as an independent cause of action). "The essence of the cause of action is that one party is enriched, and it would be unjust for that party to retain the enrichment." *Blythe Holdings, Inc. v. DeAngelis*, 750 F.3d 653, 658 (7th Cir. 2014) (internal citations omitted). Plaintiffs allege in their Master Long Form Complaint that:

> 629. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiffs made for TRT products.
>
> 630. In exchange for the payments made for TRT products, and at the time payments were made, Plaintiffs expected that TRT products were safe and medically effective treatment for the condition, illness, disorder or symptom for which they were prescribed.

> 631. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs paid for TRT products when they otherwise would not have done so. The failure of Defendants to provide Plaintiffs with the remuneration expected enriched Defendants unjustly.
>
> 632. Plaintiffs are entitled to equity to seek restitution of Defendants' wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

Master Long Form Compl. at ¶ 629-632. These allegations encompass both Besins S.A. and Besins Inc.

Between late 2010 and late 2015, Besins received royalty payments for AndroGel sales in the United States totaling $357,675,391 based on $4,596,434,028 of AndroGel sales. Ex. 13; Ex. 1 at 18:14-21:11; and Ex. 2 at 183:8-188:8. AndroGel royalties in the United States have accounted for approximately one-third of Besins' revenues. *See* Ex. 1, Besins 30(b)(6) Tr. at 23:14-26:10.

The Besins defendants knew there had been insufficient testing to evaluate the association betweenbsmit cardiovascular and VTE risks and AndroGel, but despite that knowledge decided that they should not pursue additional safety studies but, instead, continue profiting off of AndroGel sales. *See* Ex. 14.

The Besins defendants have significantly enriched themselves from the sale of AndroGel for years and under the facts of the case, it would be unjust for them to retain that enrichment. Moreover, Plaintiffs continue to pursue their unjust enrichment claims as independent causes of action, and the Besins defendants have failed to properly move for summary judgment on those claims.[5]

[5] Because the Besins defendants are not entitled to summary judgment on Plaintiffs' remaining claims, they are also not entitled to summary judgment on their wrongful death, survival, loss of consortium, and punitive damage claims (Count XI – XIV).

CONCLUSION

For the foregoing reasons, this Court should deny the Besins defendants' motion for summary judgment.

Dated: April 20, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2018, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Brendan A. Smith
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